

# REACH-IT Industry User Manual Part 06 - Dossier submission



#### **Document history**

Version	Changes
1.4	March 2010
	Update to REACH-IT 2.0
1.1	December 2009
	P 7: Text added to introduce submission pipeline flow diagram (chapter 2).
	P 8: Inclusion of a flow diagram for the submission pipeline (Figure 1: Flow diagram for dossier submission).
	P 26: Sentence on large access code added in chapter 3.1.5.
	Minor textual revisions.
	Document in new layout.
1.0	December 2008
	First version.

Reference: ECHA-08-B-14-EN Issue date: 25 March 2010

Language: English

If you have questions or comments that relate to this document, please send them using the information request form to ECHA helpdesk. Quote the reference and issue date as stated above. The information request form can be accessed via the ECHA website under the section for the REACH helpdesk at the following address:

http://echa.europa.eu/reach/helpdesk/echahelp\_en.asp

© European Chemicals Agency, 2009. Reproduction is authorised provided the source is fully acknowledged in the form "Source: European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>", and provided written notification is given to the ECHA Communication Unit (info@echa.europa.eu).

Version: 1.4 Page 2 of 41

## Part 06 - Dossier submission



### **Table of Contents**

1	Introduction	6
2	General concept of dossier submission	7
2.1	Supported dossier types	9
2.2	Submission parameters	<u> </u>
2.2.1	Data Submission process	10
2.2.2	Virus scan	10
2.2.3	File format validation	10
2.2.4	Internal structure validation	10
2.2.5	Business rules validation	11
2.2.6	Dossier storage	12
2.2.7	Substance identity creation	12
2.2.8	Assign MSCA	12
2.2.9	Technical Completeness Check (TCC)	12
2.2.1	0 Pay submission fee	12
2.2.1	1 Overall completeness check	12
2.2.1	2 Issue reference number	12
2.3	Following up on submissions	12
2.3.1	Internal message	12
2.3.2	Dossier information page and submission report	13
2.4	Submission number and reference number	13
2.4.1	Submission number	13
2.4.2	Reference number	14
2.5	External (versus internal) submissions	15
2.6	Initial submission versus Update submissions	15
2.6.1	Initial submission	15
2.6.2	Submission of spontaneous updates	15
2.6.3	Submission of updates by request	15
2.7	Cease and restart manufacture	16
2.7.1	Cease manufacture for commercial reasons	16
2.7.2	Cease manufacture upon receipt of a draft decision	16
3	Step-by-step dossier submission	17
3.1	External submission	17
3.1.1	Step 1 – starting a dossier submission	17
3.1.2	Step 2 – Selecting a dossier type	17
3.1.3	Step 3 – Uploading a dossier file	23
3.1.4	Step 4 – Confirming Dossier submission	26
3.1.5	Large file access code request	26
3.2	Search and viewing dossier details	28
3.2.1	Searching submissions	28

## Part 06 - Dossier submission



3.2.2	Dossiers information pages	31
3.3	Dossier submission failures	34
3.4	Cease and restart manufacture	36
3.4.1	Cease manufacture	
		_
3.4.2	Restart manufacture	39
Table	e of Tables	
Table	1: Overview of dossier types supported by REACH-IT	9
	2: Submission parameters to be specified	
	3: Submission steps versus submitted dossier type	
Table	4: Structure reference number	14
Table	e of Figures	
	1: Flow diagram for dossier submission	
	2: Starting a dossier submission (step 1)	
	3: Selecting a dossier type (step 2)	
	4: Specific submission parameters for registration dossiers (step 2)	
	5: Opt-in for confidentiality claim(s) (step 3)	
	7: Specific submission parameters for transported isolated intermediate registration dossiers (step 2)	
Figure	8: Specific submission parameters for a PPORD notification (step 2)	21
	9: Specific submission parameters for an inquiry notification (step 2)	
	10: Specific submission parameters for a C&L notification (step 2)	
	11: Specify if the submission is on behalf of a group	
	12: Submit external dossier page (step 3)	
	13: Dossier selection from .i5z files (step 3)	
	14: Link to locally stored .i5z file in <file name=""> data field (step 3)</file>	
	15: Dossier upload progress bar (step 3)	
Figure	16: Confirm dossier submission page (step 3)	25
	17: Successful dossier submission with submission number (step 4)	
	19: Request access code page	
Figure	20: Submission request sent page	21 27
Figure	21: Internal REACH-IT message regarding "Large file one-time access code"	28
	22: REACH-IT search function for dossiers	
	23: Submitted dossier (Search) page	
	24: Search combination for submissions	
Figure	25: Search results for submissions	30
Figure	26: Dossier details page	31
Figure	27: Request submitted file page	31
	28: Dossier submission report page	
	29: Accounting page	
	30: Annotation page	
	31: Annotation page with detailed information	
	32: Internal message with dossier submission failure details	
	33: Cease and restart manufacture menu items	
	34: Cease manufacture search tab	
	36: Cease manufacture details tab	
	37: Cease manufacture confirmation tab	
	38: Cease manufacture internal message	
	39: Restart manufacture search tab	
_	40: Restart manufacture details tab	

## Part 06 - Dossier submission



Figure 41: Restart manufacture confirmation tab	.40
Figure 42: Restart manufacture confirmation message	40
Figure 43: Restart manufacture internal message	40

Version: 1.4 Page 5 of 41

# REACH-IT Industry User Manual Part 06 - Dossier submission



## 1 Introduction

The Industry User Manual (IUM) is the reference manual that describes to industry users how they can submit and view data within REACH-IT. As REACH-IT evolves, additional and updated parts of this IUM will be released and made available via the ECHA website.

Prior to using this Part 6 (Dossier submission), it is strongly recommended that the user reads Part 1 – Getting started with REACH-IT, where the following topics are discussed in more detail:

- structure of this IUM
- conventions used, in terms of icons, text, buttons, links, ...
- background information on REACH-IT and its link to the IUCLID 5 website and application

How to get additional support is also described in Part 1. Each subsequent parts of this IUM will therefore cover the step-by-step instructions to perform the tasks required for submission of data under REACH.

Version: 1.4 Page 6 of 41



#### **General concept of dossier submission** 2

The dossier submission is one of the Industry core functionality in REACH-IT. Applicants have to submit dossiers to ECHA to fulfil the legal obligations set out by the REACH regulation.

REACH-IT supports the submission of dossier files that have been prepared outside of the REACH-IT system, in the IUCLID 5 format. For certain dossier types, REACH-IT may allow the creation and submission of dossiers inside the REACH-IT application (for example online inquiry).

You are advised to consult the documentation related to dossier submission (registration available on the ECHA website:

#### http://echa.europa.eu/help/help\_docs\_en.asp

For information purposes a high level overview of the dossier submission process is provided in Figure 1. The registration process can be presented by dividing it in four parts (A-D), each shown in the figure. Each part is discussed below:

#### Part A: Verifications

The process starts with the submission of a dossier by the registrant. The submitted dossier than undergoes a virus and XML format check and additionally a Business Rules (BR) validation. These are discussed in the chapters 2.2.2, 2.2.3, 2.2.4, 2.2.5. The results of the checks are reported in real time in the submission report, which can be consulted online or downloaded.

#### Part B (Technical Completeness Check - TCC) and part C (Invoicing):

When the dossier passed the virus plus xml checks and BR validation the dossier undergoes a Completeness Check (CC) that consisting of a technical completeness check (TCC) (part B) and, if applicable, an invoicing process (part C). Invoicing and TCC does not apply for all submitted dossiers, for example inquiries. The invoice is sent to the registrant via a REACH-IT message. More details on the process are provided in the chapters 2.2.10, 3.2.2.3 and 2.2.9.

#### Part D: End of process

If the dossier fails the CC and/or validation the dossier can not be accepted and the registrant has to submit a new initial dossier or send an update within the deadline. More details are provided in chapter 2.2.11.

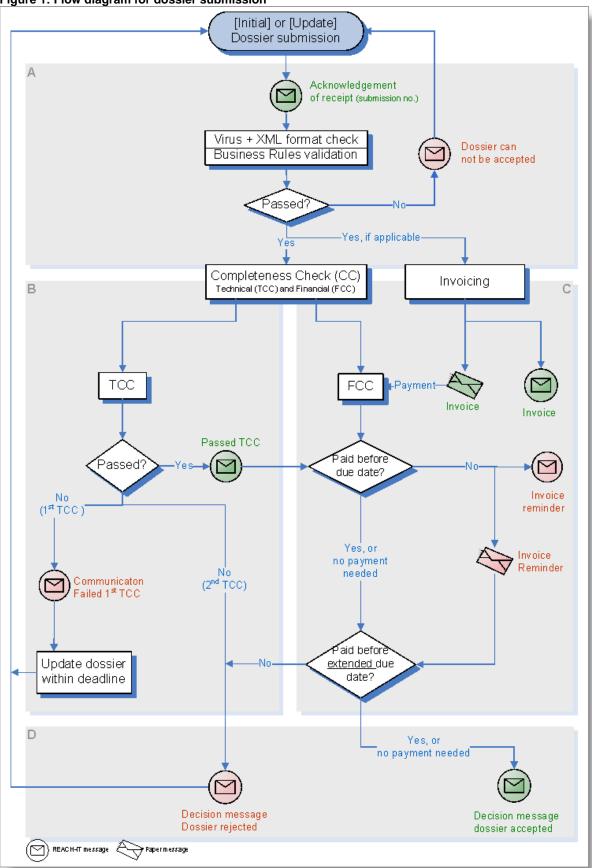


★ The result of a dossier submission (but also the main intermediates results) – either a failure or a success - will be sent as an "internal message" to the company's REACH-IT Message inbox.

Version: 1.4 Page 7 of 41







Release date: March 2010

Version: 1.4



## 2.1 Supported dossier types

Table 1 provides an overview of the supported dossier types which can be submitted via REACH-IT. Information about Joint Submissions is provided in the Industry User Manual Part 7 (Joint Submission), available from the ECHA website.

By convention, .i5z files (created in IUCLID 5) will be called "substance dossiers".

Table 1: Overview of dossier types supported by REACH-IT

Dossier type	Submission	Submission update	Joint Submission
Registration	Yes	Yes	Yes
Registration of on-site isolated intermediate	Yes	Yes	Yes
Registration of transported isolated intermediate	Yes	Yes	Yes
Process and Product Oriented Research and Development (PPORD) notification	Yes	Yes	No
Classification and Labelling (C&L) notification	Yes	Yes	Yes
Inquiry notification	Yes	No	No

## 2.2 Submission parameters

In addition to the dossier type, the applicant must specify other parameters of the submission, listed in Table 2. The submission parameters are discussed below and more information is provided for each parameter.

Table 2: Submission parameters to be specified

Dossier type		Submission parameters		
	Purchase order	No restriction statement	Inquiry statement	
Registration	0	М	NR	
Registration of on-site isolated intermediate	0	М	NR	
Registration of transported isolated intermediate	О	М	NR	
PPORD notification	0	М	NR	
C&L notification	NR	NR	NR	
Inquiry notification	NR	NR	M	

M: Mandatory submission parameter; O: optional parameter; NR: parameter not relevant for that dossier type; \*: except in the case of the submission of a registration covering both types of intermediates only.

Version: 1.4 Page 9 of 41

#### Part 06 - Dossier submission



**Purchase order**: field where a company-specific purchase order number may be entered by the applicant. This value will appear on the invoice related to that submission in order to facilitate its treatment by the billing organisation.

**No restriction statement**: this is an acknowledgement that the substance for which the dossier is submitted is not subject to any restrictions in existing legislation(s) or to any exemptions under REACH.

#### 2.2.1 Data Submission process

The submission of a dossier and its subsequent processing by REACH-IT is a complex procedure that is executed as a series of steps. The different submission steps are listed below (Table 3) in relation to the type of submitted dossier.

Table 3: Submission steps versus submitted dossier type

Submission step	Registration (all kinds)	PPORD notification	Inquiry notification	C&L notification
Virus scan	Υ	Υ	Υ	Υ
File format validation	Υ	Υ	Υ	Υ
Internal structure validation	Υ	Υ	Υ	Υ
Business rule validation	Υ	Υ	Υ	Υ
Dossier storage	Υ	Υ	Υ	Υ
Substance identity creation	Υ	Υ	Υ	Υ
Assign MSCA	Υ	Υ	N	N
Technical Completeness Check	Υ	Υ	N	N
Pay submission fee	Υ	Υ	N	N
Overall completeness check	Υ	Υ	N	N
Issue reference number	Υ	Υ	N*	Υ

Step occurs: Y= yes, N = no;

#### 2.2.2 Virus scan

The submitted dossier file is scanned for known viruses. Only virus-free dossier files will proceed to the next step.

#### 2.2.3 File format validation

The file format validation is verification that the submitted dossier file is of the appropriate format (.i5z file format) and is compliant with the XML schema used by IUCLID 5.

#### 2.2.4 Internal structure validation

This verification ensures that the submitted dossier file does not contain attachments for which the format is not supported/recognised by REACH-IT. Only after that step can REACH-IT proceed with the actual validation of the submission. This step consists only in a warning in case your dossier contains unsupported file types. However, your dossier will never be rejected at this step and will continue to be processed.

Version: 1.4 Page 10 of 41

<sup>\*</sup> given during the inquiry process not during submission.

#### Part 06 - Dossier submission



- If the format of the file sent is not supported and/or recognised by REACH-IT, your dossier is still processed but the following message is sent to your REACH-IT message box: "Your submission contained unsupported attachment file type(s). [...] Please note! Your submission is still being processed. During further processing the file type may cause non acceptance of the submission. In that case ECHA will inform you thereof and you may have to resubmit the dossier."
- The list of supported attachment file types are: txt, doc, jpeg, tiff, mol, pdf, jpg and rtf (in addition, the following file types are also accepted in Inquiry notifications: asp, htm and html).

#### 2.2.5 Business rules validation

Consequently, REACH-IT verifies that the submission is correct according to predefined "business rules". This is a prerequisite to further proceed with a dossier submission. Examples of business rules are:

- The same dossier (for example same dossier UUID) has not been submitted already.
- The dossier type is correct, for example the dossier type indicated as a submission parameter is consistent with the dossier type found inside the submitted dossier file.
- The format of the C&L section is valid.
- The dossier contains a correct reference to a pre-registration number or an inquiry number
- When the dossier is from a Member of a Joint Submission, it is to be submitted only after successful submission of the Lead dossier.
- When the dossier is an update dossier, it contains all appropriate references to the previous submission number, and, when necessary, to the previous decision number, and, if available, to the reference number.
- The update of the dossier is submitted within the deadline.
- A business rule may either succeed or fail. Only in the cases where a mandatory or optional business rule fails, you can view it in the submission report. The confirmed failures of overrulable business rules are available in a communication attached to your dossier.
- For mandatory rules, the business rule failure is highlighted in red (Figure 28). For optional rules, the business rule failure is highlighted in orange (Figure 28). Business rules were put in place to ensure the consistency of submissions.
- The consequence of business rule failure depends upon the level of the rule:
  - When a business rule is optional, failure is turned into a weak warning in the submission report but the overall submission is not impacted and your dossier is still processed.
  - When a business rule is mandatory, failure results in the failure of the submission.
  - When a business rule can be overruled, failure can still be accepted (or rejected) by ECHA after manual verification of the dossier.
- When all business rules have either succeeded or been manually overruled, the submission proceeds to the next steps. Otherwise, the submission fails and ends here.

Version: 1.4 Page 11 of 41

#### Part 06 - Dossier submission



More details on BR validation can be found in Data Submission Manual 8 – Business Rule validation available on the ECHA website.

#### 2.2.6 Dossier storage

Dossiers which have a correct structure and have passed the business rules check are stored in the REACH-IT database.

#### 2.2.7 Substance identity creation

A substance identity is assigned to the substance included in the dossier. The rules that govern the creation of a substance identity rely on the content of the substance documented in the dossier (.i5z file), and are very directly related to the IUCLID 5 sections 1.1 'Identification' and 1.2 'Composition'.

#### 2.2.8 Assign MSCA

At that stage, the 'concerned' Member State Competent Authority (MSCA) are identified by the system from the relevant parts of the dossier and based on the information sent with the dossier. Depending on the dossier type, this can be determined based on the country where the manufacturing site, notifier or user is located. Consequently the MSCA will be informed via REACH-IT that a dossier was submitted and in future stages, about the status of the submitted dossier.

#### 2.2.9 Technical Completeness Check (TCC)

The Technical Completeness Check (TCC) of the dossier is performed and may succeed or fail. At this stage, all required information is verified.

#### 2.2.10 Pay submission fee

Depending on the submitted dossier (Table 3) and if relevant, a submission fee is calculated and an invoice is generated for the submission.

#### 2.2.11 Overall completeness check

When both the TCC is successful and the invoice is paid, the submission is considered successful and can proceed. This step is called the "overall completeness check".

#### 2.2.12 Issue reference number

At the end of a successful initial submission, the substance is given a reference number depending on the dossier type (for example a registration number) according to a predefined format (see chapter 2.4).

### 2.3 Following up on submissions

#### 2.3.1 Internal message

Every main steps of the dossier submission processing will generate an internal message sent to the applicant's internal REACH-IT message box. These messages are related to:

**Submitted file received**: this message is sent as soon as the dossier file has been received and a submission number has been given to the submission.

**Submission failure / submission rule violation**: this message is sent when a business rule violation is detected.

**Reference number assigned**: this message is sent, at the end of the successful submission process, once a reference number is given to the submitted substance (this step is not performed for updates, instead, the previously assigned reference number is retrieved).

Version: 1.4 Page 12 of 41

## **REACH-IT Industry User Manual** Part 06 - Dossier submission



Successfully reached the end of the dossier processing: this message is sent at the end of a successful submission process.

Each message includes a hyperlink to the dossier information page and/or submission report.

### 2.3.2 Dossier information page and submission report

The time necessary for the processing of a submission may vary (days to weeks, depending on the TCC and/or invoicing steps). However the registrant can follow at any time the progression of his/her submission, either in the dossier information page or in the submission report (Figure 28).

The dossier information page and/or the submission report are directly available by activation of a hyperlink in an internal message, or by searching for a given submission.

The dossier information page contains the following sections (= tabs) (Figure 20 to Figure 23):

- <Details>: a summary of key dossier information.
- <Submission report>: the complete submission report. It shows the situation of a submission at the moment it is consulted. It can be saved as a PDF document.
- <Accounting>: if applicable, the accounting information pertaining to the submission.
- <Annotations>: the dossier annotations related to that submission are a full part of the information and comprise decisions and communications (see chapter 3.2.2.4), issued by ECHA to the company, on the submitted dossier. Annotations cover also opinions and comments which are issued by Authorities, opinion being an official position of, for example a MSCA.

#### 2.4 Submission number and reference number

#### 2.4.1 **Submission number**

A submission number is a unique number assigned automatically after successful business rule validation and generated per each submission by REACH-IT as mentioned in Article 20 (REACH Regulation).

A preliminary submission number is assigned to the dossier at the time of uploading it to REACH-IT. Consequently, the submission date is only set after the completion of business rule validation. The upload date, which is set directly after successful upload of the dossier via the submission page, is visible until the submission date has been set.

The submission number has the following characteristics:

- It is a unique number generated for each submission, and which has a specific format.
- It is issued for every submission, whatever the type of submission or its status.
- It does not provide any information regarding the dossier type, or company information, or any other characteristic of the submission.

The structure of a submission number is as follows: the submission number is issued at every submission using the following unique format: 2 uppercase letters, 6 digits, a hyphen and two digits (for example RX120340-22); the last two digits being used as checksum which allows for error detection.

The submission number will be used in all further communications from REACH-IT to

Version: 1.4 Page 13 of 41

#### Part 06 - Dossier submission



the user concerning the corresponding dossier.

#### 2.4.2 Reference number

A reference number has been coined as a more general designation than registration number or notification number and represents a unique number which is generated by REACH-IT and given to a substance and a company after dossiers of certain types are successfully submitted for the first time. Such a reference number is generated at the submission of:

- A registration dossier: the registration number (as per REACH Article 20(3)).
- A PPORD notification: the PPORD notification number (as per REACH Article 9(3)),
- A C&L notification: the C&L notification number,
- An inquiry: the inquiry number,
- A pre-registration: the pre-registration number.

The reference number is only issued once at the end of the initial and successful submission process. The reference number is a unique number generated per dossier type, per substance and per company.

This number will be unique for every company and every substance. The structure of the reference number will be: <TYPE>-<BASE NUMBER>-<CHECKSUM>-<INDEX NUMBER>. Table 4 shows the details for each structure element.

Table 4: Structure reference number

Structure	Element
<type></type>	is a 2-digit number giving the type of number:
	01 Registration
	02 C&L notification
	03 Substance in article
	04 PPORD
	05 Pre-registration: (reserved to pre-registrations according REACH §28 (2))
	06 Inquiry
	07 On-site isolated intermediates*
	08 Transported isolated intermediates*
	09 Data Holder notification
	10 Downstream User notification
	11 Application for Authorisation
	12 Substance Evaluation
	13 Annex XV – C&L Harmonization
	14 Annex XV – Authorisation
	15 Annex XV – Restriction
	16 Internal usage
	17 Late Pre-registration: (reserved to pre-registrations according to REACH Regulation Article 28 (6))
<base-number></base-number>	is a 10-digit number generated randomly.
<checksum></checksum>	is a 2-digit checksum computed using only <type> and <base-number>, which allows for error detection.</base-number></type>
<index-number></index-number>	is a 4-digit number that can be used to indicate the index of a Member in a Joint Submission.

Version: 1.4 Page 14 of 41

#### Part 06 - Dossier submission



## 2.5 External (versus internal) submissions

REACH-IT supports the submission of dossier files that have been prepared in IUCLID 5, outside of the REACH-IT system. This type of submission is called an "external submission".

Future releases of REACH-IT are expected to allow the creation and submission of some dossier types, directly within the REACH-IT application. This type of submission is called an "internal submission" and for example the creation of an online inquiry dossier can be done in REACH-IT.

## 2.6 Initial submission versus Update submissions

REACH-IT makes a distinction between the "initial" submissions and "update" submissions. The "initial" submission is the first submission of a dossier type (for example a registration) for a substance. The "update" submissions are all subsequent submissions of the same dossier type for that same substance. Therefore an update submission always takes place after the initial submission is completed.

The reasons for the submission of an update dossier are classified as either "spontaneous" or "by request".

#### 2.6.1 Initial submission

At the end of the very first successful submission for a substance, the applicant receives:

- A submission number for that submission, for example RX120340-22.
- A reference number for the substance and that particular submission type, for instance 01-2114367598-30-0000 for a registration.

### 2.6.2 Submission of spontaneous updates

Spontaneous updates can be made in situations such as:

- Change of tonnage band
- Change in classification
- Change in composition
- etc.
- Spontaneous registration updates are legally required under REACH Regulation Article 22(1).

#### 2.6.3 Submission of updates by request

'By request' updates are updates made to provide information explicitly requested by ECHA. Such information request may happen for example after the evaluation of a testing proposal or after a dossier compliance evaluation. In this case, the communication or decision number has to be quoted so to associate the update submission with the communication or decision issued by ECHA.

Any dossier update, either submitted spontaneously or "by request", will undergo the business rules validation steps again. This will cover all aspects of the dossier and not only the ones for which an update has been submitted. That is why an update shall always contain all the information available for that substance.

Version: 1.4 Page 15 of 41

# REACH-IT Industry User Manual Part 06 - Dossier submission



#### 2.7 Cease and restart manufacture

REACH-IT provides functionality to inform ECHA of cease and restart manufacture. The consequences of cease manufacture depend on the context in which cease manufacture is claimed by the registrant. These consequences are described in chapters 2.7.1 and 2.7.2.

#### 2.7.1 Cease manufacture for commercial reasons

Pursuant to REACH Regulation Article 50(2), if a registrant has ceased the manufacture (e.g. for commercial reasons), he shall inform ECHA of this fact with the following consequences:

- The registered volume is updated to zero, the registration's status is marked inactive but it remains a valid registration.
- The registrant will not be requested to provide further information regarding the registered substance.
- The registrant may continue acting as the lead registrant for a joint submission if he so chooses.
- The registrant may restart manufacture of the substance by simply notifying the Agency of this (no additional fee will be charged).
- The Agency shall inform the relevant MSCA.

#### 2.7.2 Cease manufacture upon receipt of a draft decision

Pursuant to REACH Regulation Article 50(3), if a registrant decides to cease manufacture upon the receipt of a draft decision, he shall inform ECHA of this fact with the following consequences:

- The registration will no longer be valid and its status will be marked revoked.
- The registrant will not be requested to provide further information regarding the registered substance.
- If the registrant is the lead registrant of a joint submission, he will have to give up this lead registrant role using the Assign New Lead functionality as explained in the IUM Part 7 – Joint Submission before ceasing manufacture.
- The registrant may only restart manufacture of the substance by submitting a new registration.
- The Agency shall inform the relevant MSCA.

Version: 1.4 Page 16 of 41



#### Step-by-step dossier submission 3

#### **External submission** 3.1

Advanced search: allows the user to search via a combination of domain and query types. The domain is first defined to help the user decide what area of information in REACH-IT is to be searched. Then the query is a more specific and detailed area of the domain.



1 The upload of dossiers with file size above 20 MB (Megabytes), has first to be approved by ECHA.

#### Step 1 – starting a dossier submission 3.1.1

To start the dossier submission, go to the <Registration/notification> menu, and click on <Submit registration / notification> (Figure 2).

Figure 2: Starting a dossier submission (step 1)



As there is no possibility to save the submission process and continue it at a later stage, you should have all required information available, as well as the export file of the dossier prepared in IUCLID 5 for your substance, before you initiate the first step of a submission. The <Submit Dossier intro> page opens after the menu selection (Figure 3).

#### 3.1.2 Step 2 – Selecting a dossier type

Select the appropriate dossier type from the <Dossier type> drop-down menu (Figure 3).

Version: 1.4 Page 17 of 41

#### Part 06 - Dossier submission



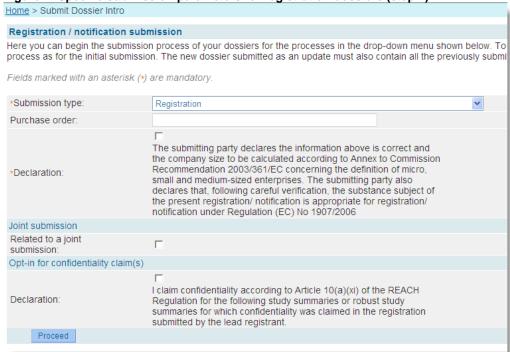
Figure 3: Selecting a dossier type (step 2)



The dossier types are discussed in chapter 2.1. Depending on the dossier type you need to submit, different additional required submission parameters (mandatory and not mandatory) will be requested.

#### 3.1.2.1 Submitting a Registration dossier

Figure 4: Specific submission parameters for registration dossiers (step 2)



**Purchase Order:** Where needed, fill in with the appropriate reference to be used by ECHA during the generation of the invoice related to your submission.

**Declaration**: Click the checkbox related to the statement agreement (entirely reported here below), for registration submissions (registration dossier, or registration dossier of on-site isolated intermediate, or registration dossier of transported isolated intermediates): "The submitting party declares the information above is correct and the company size to be calculated according to Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small, medium and large-sized enterprises. The submitting party also

Version: 1.4 Page 18 of 41

#### Part 06 - Dossier submission



declares that, following careful verification, the substance subject of the present registration/ notification is appropriate for registration/ notification under Regulation (EC) No 1907/2006".

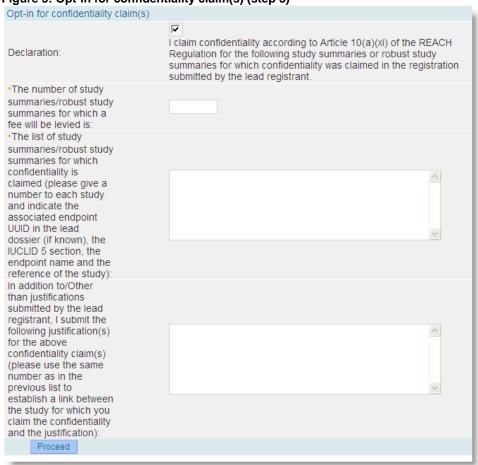
**Opt-in for confidentiality claim(s)**: Click the checkbox wherever applicable.

In case you are a Member of a Joint Submission, and would like to confirm that you want to keep confidential (robust) study summaries (from IUCLID sections 4 to 7) submitted by the Lead of the Joint Submission, you have to click the check box related to the declaration for confidentiality, and fill-in the following fields that are displayed (Figure 5).



This is only applicable in the case of a Member of a Joint Submission.

Figure 5: Opt-in for confidentiality claim(s) (step 3)



Fill in all fields, related to the number and list(s) of studies for which confidentiality is claimed, as well as the justifications for each claim if it differs from the justification provided in the Lead dossier (Figure 6). When all relevant data entry fields are completed (Figure 4 to Figure 5), click on <Proceed> to go to the next step.

Version: 1.4 Page 19 of 41



# 3.1.2.2 Submitting a Registration dossier of an on-site/transported isolated intermediate

Some of the fields you have to fill in are identical as the ones for a full registration dossier (Figure 6 and Figure 7).

Figure 6: Specific submission parameters for on-site isolated intermediate registration dossiers (step 2)

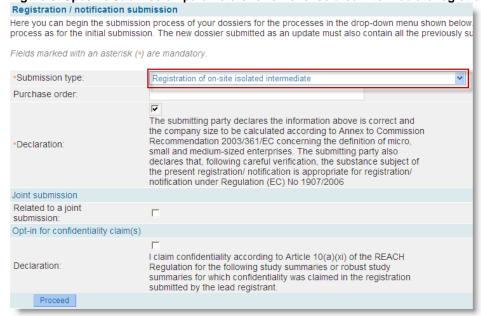


Figure 7: Specific submission parameters for transported isolated intermediate registration dossiers (step 2)



**Purchase Order**: Where needed, fill in with the appropriate reference to be used by ECHA during the generation of the invoice related to your submission.

**Declaration**: Click the checkbox related to the statement agreement for registration dossiers of on-site isolated intermediates, or of transported isolated intermediates.

Version: 1.4 Page 20 of 41

#### Part 06 - Dossier submission



Opt-in for confidentiality claim(s): Click the checkbox wherever applicable.

In case you, as a Member of a Joint Submission, would like to confirm that you want to keep confidential (robust) study summaries (from IUCLID sections 4 to 7) submitted by the Lead of the Joint Submission, you have to click the check box related to the declaration for confidentiality, and fill-in the following fields that are displayed (Figure 5).



This is only applicable in the case of a Member of a Joint Submission (for example not for the Lead).

When all relevant data entry fields are completed (Figure 6 and Figure 7), click on <Proceed> to go to the next step.

#### 3.1.2.3 Submitting a PPORD notification

Some of the fields you have to fill in are identical as the ones for a full registration dossier (Figure 8).

Figure 8: Specific submission parameters for a PPORD notification (step 2)



Purchase Order: Where needed, fill in with the appropriate reference to be used by ECHA.

**Declaration**: Click the checkbox related to the statement agreement.

#### 3.1.2.4 Submitting an Inquiry notification

Some of the fields you have to fill in are identical as the ones for a full registration dossier (Figure 9).

Figure 9: Specific submission parameters for an inquiry notification (step 2)



Click on <Proceed> to go to the next step.

Version: 1.4 Page 21 of 41

#### Part 06 - Dossier submission



#### 3.1.2.5 Submitting a C&L notification

**Quantity produced or imported:** Indicate the volume range of the substance notified and the year.

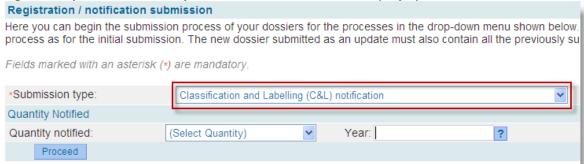
In the case the substance you notify is subject to registration in accordance with the REACH Regulation, please indicate in this field the volume range produced or imported.

In the case the substance you notify is a hazardous substance placed on the market either on its own or in a mixture, please indicate in this field the volume range of the substance marketed.

This information is not mandatory and will, if provided, not be published on ECHA website but used for internal statistic only.

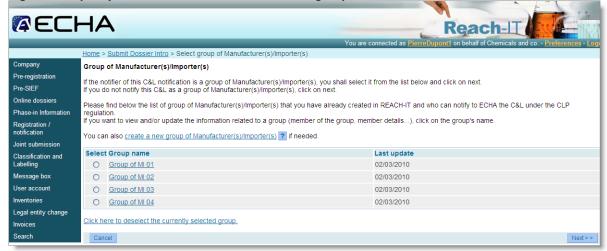
Please be aware that if you decide to provide this information, both fields, quantity and year, need to be filled.

Figure 10: Specific submission parameters for a C&L notification (step 2)



When completed (Figure 10), click on <Proceed>, you will then be asked to specify if you submit the C&L notification on your own or on behalf of a group of Manufacturers and/or Importers (group of MI) (Figure 11).

Figure 11: Specify if the submission is on behalf of a group



On this screen, you can:

select a group of MI and assign it to your submission

Version: 1.4 Page 22 of 41

Part 06 - Dossier submission



- continue without selecting a group of MI, by clicking <next>
- · create a new group

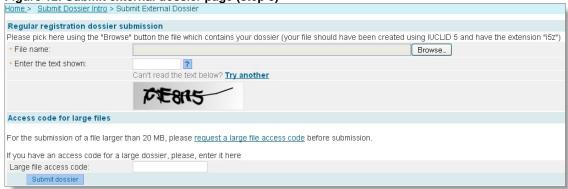
For more details on the functionalities offered in this screen, please consult IUM – part 15 on "How to create and manage your group of manufacturers or importers" for C&L notification submission.

When completed, click on <next> to go to the next step.

#### 3.1.3 Step 3 – Uploading a dossier file

For any dossier type described in Step 2, the dossier upload page opens (Figure 12). Fill in the mandatory fields (\*) related to the file name and the CAPTCHA text.

Figure 12: Submit external dossier page (step 3)



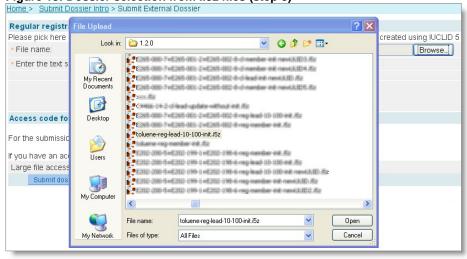
Click on <Browse> to open a dialogue box which allows you to select the dossier file you want to upload (Figure 13). Your substance file must have already been created in IUCLID 5 and have the extension '.i5z'. More information about IUCLID and dossier creation can be found in the UCLID 5 user manual.

Version: 1.4 Page 23 of 41

#### Part 06 - Dossier submission



Figure 13: Dossier selection from .i5z files (step 3)



Only one .i5z file can be selected. Now select the file (dossier) you want to submit and click on <Open>. You will see the link to your locally stored .i5z file, appear in the <File name> field (Figure 14).

Figure 14: Link to locally stored .i5z file in <File name> data field (step 3)



Enter the CAPTCHA text shown (\*).

The upload of dossiers, with file size above 20 MB, has first to be approved by ECHA. Click on <request a large file access code> (Figure 14).

More details are given in chapter 3.1.5 on how to obtain a large file access code from ECHA. Then click on <Submit dossier>. After submitting the dossier, a progress upload bar opens, showing the status of the upload process (Figure 15).

Version: 1.4 Page 24 of 41

#### Part 06 - Dossier submission



Figure 15: Dossier upload progress bar (step 3)

100 DE 100 MANAGEMENT SO CASO	o > Submit External Dossier
Here you can submit a PPC	PRD notification dossier.
Product and Process Or	ientated Research and Development (PPORD) notification submission
Please pick here using the 5 and have the extension "i	"Browse" button the file which contains your dossier (your file should have been created using IUCLID 5z")
	100%
* File name:	Please wait! The file is being uploaded.  Do not close the browser or navigate to a different page.  Otherwise the submission will be cancelled.
* Enter the text shown:	8274f Can't read the text below? Try another
Access code for large fil	les
For the submission of a file	larger than 20 MB, please <u>request a large file access code</u> before submission.
If you have an access code	for a large dossier, please, enter it here
Large file access code:	
Submit dossier	

When the dossier file has been uploaded, the <Confirm Dossier Submission> page opens (Figure 16).

Figure 16: Confirm dossier submission page (step 3)

lome > Submit Dossier Intro > Confirm Dos	DIEL GUNIIII991011
Confirm Dossier Submission	
Dossier type:	Registration (regular)
Dossier file name:	for versionsinitial_dossier_vanadium_with_customers_no1.i5
Organisation Name:	HOFFSTADT-ECHA-SAT
Company size:	Medium
Invoice Contact Name:	Helene HOFFSTADT
Tonnage band:	Between 100 to 1000 tonnes/year
On-site Isolated Intermediates Tonnage band:	; <del>*</del>
Transported Isolated Intermediates Tonnage band:	<b>∞</b>
Fee Waiver:	No
Phase-in:	Yes
Legal entity change	
Legal entity change:	No
Submission number given to previous legal entity:	(2)
Reference number given to previous legal entity:	
Acquisition of rights to a previous submission:	
Confidentiality claim(s)	
Declaration:	No
Number of study summaries/robust study summaries for which a fee will be levied:	
_ist of study summaries/robust study summaries for which confidentiality is claime Submitting justification(s) for the above	d: T
confidentiality claim(s):	*
Confirm submission Cand	el submission el submission

Carefully verify your data and, on approval, click on <Confirm submission> to finalise the dossier submission. If you decide not to proceed with the submission, click on <Cancel

Version: 1.4 Page 25 of 41

#### Part 06 - Dossier submission



submission> and the uploaded information will not be stored in the REACH-IT system as you have terminated the submission process.

#### 3.1.4 Step 4 – Confirming Dossier submission

The dossier submission successful page opens (Figure 17) after you confirm the submission. It shows a confirmation message and provides your submission number. An internal message is simultaneously sent to your REACH-IT Message box.

Figure 17: Successful dossier submission with submission number (step 4)





Save your submission number as you might need it for further communication.

If you click on <Message box>, you will have access to the submission report (Click on <Download submission report>) (Figure 18).

Figure 18: View in message box page



#### Large file access code request 3.1.5

In Step 3 - Uploading a dossier file, you may need to submit a large file (> 20MB). In that case you first have to request an access code via the link <Request a large file access code> before you can proceed with the submission.

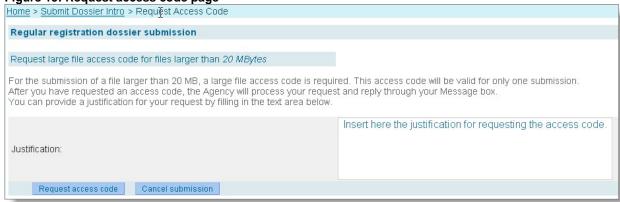
Click on <Request a large file access code> (Figure 12). A new page will open (Figure 19) where you must enter a justification for the request.

Version: 1.4 Page 26 of 41

# REACH-IT Industry User Manual Part 06 - Dossier submission



Figure 19: Request access code page



Then click on <Request access code>. You may cancel your request by clicking on <Cancel submission>. The large file access code will be sent to your REACH-IT Message box. This code can only be used for one submission. A confirmation message will appear which confirms that the request was sent successfully (Figure 20).

Figure 20: Submission request sent page

Home > Submit Dossier Intro > Submission Request Sent

Large file access code request sent successfully

Transported isolated intermediate (T.I.I.) registration dossier submission

You will receive the Agency's reply in your Message box

After ECHA has granted the request, the access code is sent to the user's internal message box (Figure 21).

Version: 1.4 Page 27 of 41

#### Part 06 - Dossier submission



Figure 21: Internal REACH-IT message regarding "Large file one-time access code"



The large file access code can be used one-time and needs to be inserted (copy-paste) in the relevant field when submitting a large submission file (Figure 12). If you want to submit another submission dossier which file is larger than 20 mb, you need to request a new one large file access code.

## 3.2 Search and viewing dossier details

#### 3.2.1 Searching submissions

REACH-IT provides two complementary mechanisms to search dossiers or submissions. They are described below (simple and advanced search) and in more detail in part 9 (Advanced search) of the REACH-IT Industry User Manual.

**Simple search**: dossiers submitted by a company can be retrieved according to a series of simple search criteria such the submission number, the type of dossier, the status of the submission.

**Advanced search**: allows the user to search via a combination of domain and query types. The domain is first defined to help the user decide what area of information in REACH-IT is to be searched. Then the query is a more specific and detailed area of the domain.



An industry user is always allowed to search among his own dossiers, submitted to ECHA, and cannot view/search any other submissions.

To use the "simple" search functionality, select the <View registration / notification> from the <Registration / notification> menu (Figure 22).

Version: 1.4 Page 28 of 41

#### Part 06 - Dossier submission

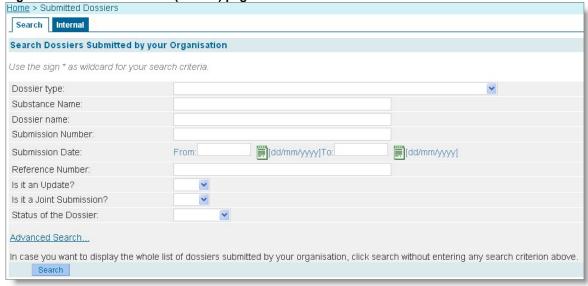


Figure 22: REACH-IT search function for dossiers



The search page is displayed (Figure 23), which gives you the possibility to search dossiers submitted by your company only.

Figure 23: Submitted dossier (Search) page



Some search entry fields are predefined via drop-down menus (for example <Dossier type>) while others are free entry fields (for example <Substance Name> or <Dossier name>). The <Submission Number> is a unique identifier and is given at the beginning of a new dossier submission via REACH-IT. The <Submission Date> allows you to use a date range to search for a dossier. The <Reference number> can be used to search for dossiers that successfully reached the end of the submission process or to retrieve updates. Two questions are added <Is it an Update?> and <Is it a Joint Submission?> to allow searching for dossier updates and dossiers sent within a Joint Submission. Finally the <Status of the Dossier> can be selected from a drop-down menu that contains 'complete', 'pending' and 'failed'. Wild cards (\*) are allowed in the text fields.

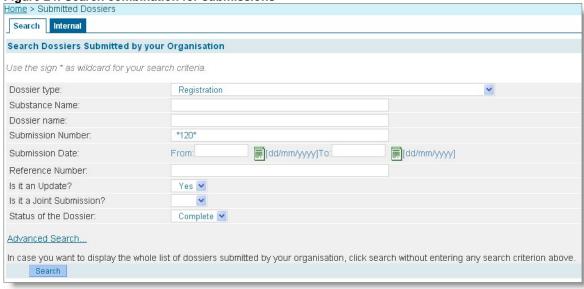
Figure 24 shows the example of a search for complete update registration dossiers having a submission number containing the number '120'.

Version: 1.4 Page 29 of 41

#### Part 06 - Dossier submission

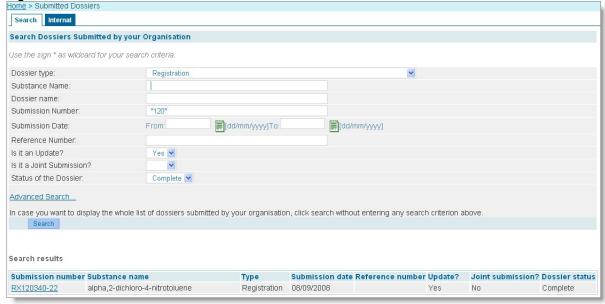


Figure 24: Search combination for submissions



Then click on <Search>. The submission(s) matching the search criteria is (are) displayed, in <Search results>, at the bottom of the screen (Figure 25).

Figure 25: Search results for submissions



In the column "Submission number", if you click on the link, <Dossier Details> page and its four tabs opens (<Details>, <Submission Report>, <Accounting> and <Annotations>) (Figure 26).

Figure 24 and Figure 25 also show a link <Advanced search ...>. Details on this function are given in 'Part 9 – Advanced Search' of the Industry User Manual available on the ECHA website.

Version: 1.4 Page 30 of 41

#### Part 06 - Dossier submission



#### 3.2.2 Dossiers information pages

#### 3.2.2.1 Details tab

A summary of key dossier information, related to the dossier type, the submission and the substance, is provided in the <Details> tab (Figure 26 and Figure 27).

Figure 26: Dossier details page



The <Request submitted file> button gives you the option to request the file that was uploaded during the submission process. You must provide a justification with your request. The justified request is sent to a dossier manager in ECHA.

Figure 27: Request submitted file page



You will receive a response in your REACH-IT Message box. If your request is approved, you will be able to download the file to your local system.

#### 3.2.2.2 Submission Report tab

The Dossier Submission Report tab shows the status of a submission at the time of consultation. It displays submitted substance and dossier information, as well as completed tasks. Click on <Download submission report> (Figure 28) to save this report as a PDF document.

Version: 1.4 Page 31 of 41

# REACH-IT Industry User Manual Part 06 - Dossier submission

## AECHA http://echa.europa.eu

Submission Rep	ort - ZN124890-15		
ubmission report			
ossier type	Registration		
ubmission number:	ZN124890-15		
reference date:	4		
Reference number: Submission date:	05/12/2008		
Current state:	Failed		
ubmitted information			
onnage band:	Between 100 to 1000 to	nnes/yean	
On-site isolated Intermediates tonnage	ie.		
and:			
Fransported isolated ntermediates tonnage pand:	(Z)		
s phase in:	Yes		
Purchase order:	(e)		
ee walver.	No PUB TIDO UCOS TOSO	initial disclor consolium with customers	- 601 157
ossier file name:	SUB_PPU_0602_1620	_initial_dossler_vanadium_with_customer	2_HET 10Z
ossier content			
lossier information			
Dassier UUID :	IUC5-1d080d6a-550c-4	b6f-b327-197327f80370	
Dossier creator.	F		
lossier subject			
lame given by the lossier creator	SUB_PPD_UC02_TC20	_initial_dossler_vanadium_with_customer	5_no1 i5z
Submitting legal entity:	HI SHATT-ECHA-SA	T	
37/, 17/	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
egal entity change			
egal Entity Change:	No		
Submission number given to previous legal entity	÷		
Reference number given to previous legal entity:	导		
Declaration of acquisition of rights to a previous submission:	(#		
ype of submission			
Submission of an			
ıpdate			
s the submission an update?:	No		
ee calculation information			
Joint submission:	No		
Company Size:	Medium		
nvoice contact name			
nvoice fax number:	1		
Declaration:	No		
Number of study summaries/robust study summaries:	ā.		
list of study summaries/robust study			
summanes/robust study summaries:	200		
Justification(s) for the above confidentiality claim(s):	=		
assed Tasks			
No. Task		Remark	Result
t. Virus check		remark.	Succeeded
		-	Succeeded
3. Check XML structure		*	Succeeded
<ol> <li>Enforce Rules</li> <li>Rule Name: SUB GBL U</li> </ol>	202 8010	(8)	Failed
Rule Level: Mandatory	SU2_UR10		
Rule Result Not Satisfied	er type specified during the creation	n of the submitted dossier is not equal to t	he dossier type mentione
Rule Level: Optional			
Rule Result: Not Satisfied			
		ot the same as the company recorded in F your dossier will continue to be processed	

Version: 1.4 Page 32 of 41

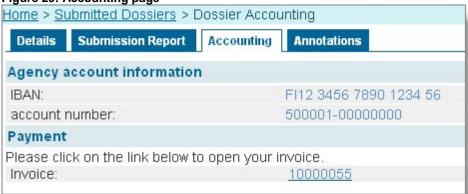
#### Part 06 - Dossier submission



#### 3.2.2.3 Accounting tab

If applicable, this tab shows the accounting information pertaining to the submission. This includes the Agency account information and the invoices linked to your dossier. Click on the invoice number link to see the invoice details (Figure 29).

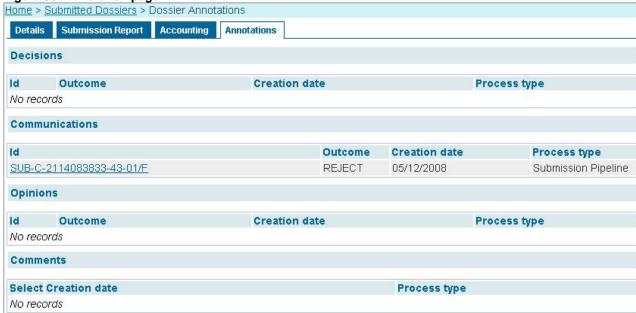
Figure 29: Accounting page



#### 3.2.2.4 Annotations tab

The Dossier Annotations tab shows annotations related to decisions, communications, opinions and comments provided by ECHA. Each annotation is identified by an "annotation number" (Id) (Figure 30).

Figure 30: Annotation page



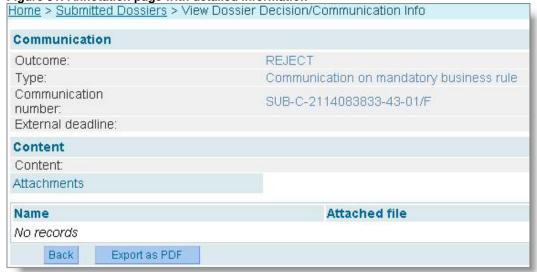
Click on the annotation number link to see details on the chosen annotation (Figure 31).

Version: 1.4 Page 33 of 41

#### Part 06 - Dossier submission



Figure 31: Annotation page with detailed information



Click on <Back> to go back to the Annotations tab (Figure 30). And click on the <Export as PDF> button to download the annotation in PDF format (Figure 31).

#### 3.3 Dossier submission failures

A submission failure is always communicated via an internal message in your REACH-IT Message box.

Click on the link <Show> and the message details will be displayed (Figure 32), for example the dossier violates a business rule, is technically incomplete (Technical Completeness Check) or the file format is invalid (see chapter 2.2.4). An explanation for the dossier failure is given in the message. The information provided in the message is only a summary.

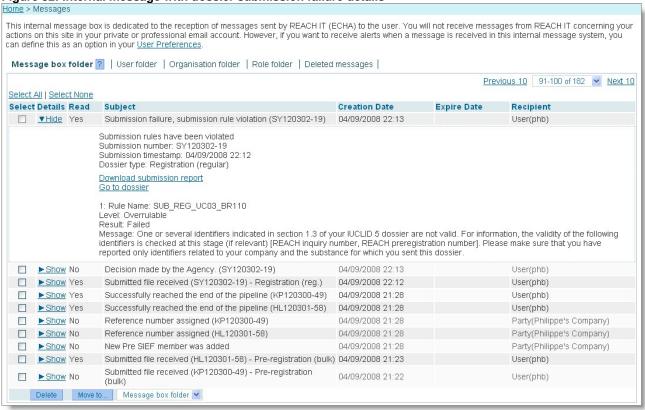
For more details, you can <Download submission report> (in .pdf format) or you can <Go to dossier> to consult the complete dossier information.

Version: 1.4 Page 34 of 41

Part 06 - Dossier submission



#### Figure 32: Internal message with dossier submission failure details



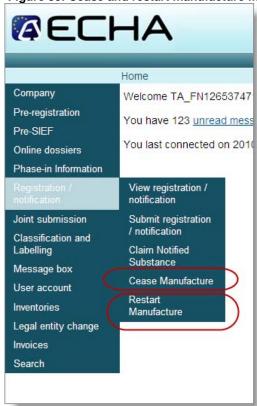
Version: 1.4 Page 35 of 41



## 3.4 Cease and restart manufacture

In REACH-IT the cease and restart manufacture functionalities are located on the main menu as indicated in the figure below. Chapter 2.7 explains the general concepts of cease and restart manufacture.

Figure 33: Cease and restart manufacture menu items



Version: 1.4 Page 36 of 41



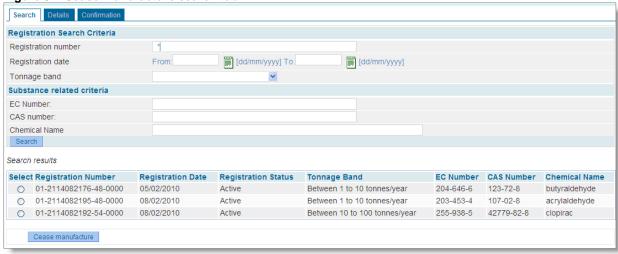
#### 3.4.1 Cease manufacture

Click the <Cease manufacture> menu item.

REACH-IT will direct the user to a search screen where you can search for all the active registrations your company currently has by using the search criteria provided.

Enter desired search criteria and click the <Search> button. The system will display all the registration for which you can claim cease manufacture, i.e. your active registrations.

Figure 34: Cease manufacture search tab



Select the registration for which you wish to claim cease manufacture for and click the <Cease manufacture> button. The system will direct you to the <Details> tab.

Figure 35: Cease manufacture details tab



Read and agree with the declaration by ticking the checkbox. Click the <Next> button. The system will direct you to the <Confirmation> tab.

Version: 1.4 Page 37 of 41

#### Part 06 - Dossier submission



Figure 36: Cease manufacture confirmation tab



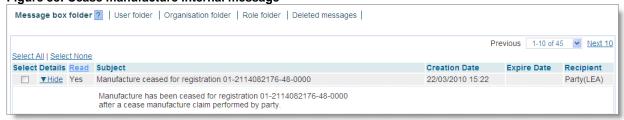
On the <Confirmation> tab, confirm your intention to cease manufacture for the selected registration by ticking the checkbox. Click the <Cease manufacture> button. The system will confirm that you have successfully ceased manufacture.

Figure 37: Cease manufacture confirmation message



You will also receive an internal message confirming the cease manufacture in your internal message box.

Figure 38: Cease manufacture internal message





A lead registrant may continue acting as a lead on behalf of his joint submission even though he decides to cease manufacture under REACH Regulation Article 50(2). However, in the event that he want to give up this role he may do so by using the Assign new lead functionality (explained in IUM Part 7 – Joint submission).



The system will not allow cease manufacture for a lead registrant who has received a draft decision. Before being able to cease manufacture in this situation, the lead registrant must relieve himself of this lead role using the Assign new lead functionality (explained in IUM Part 7 – Joint submission).

Version: 1.4 Page 38 of 41

#### Part 06 - Dossier submission



#### 3.4.2 Restart manufacture

Click the <Restart manufacture> menu item.

REACH-IT will direct the user to a search screen where you can search for all the inactive registrations your company currently has by using the search criteria provided.

Enter desired search criteria and click the <Search> button. The system will display all the registration for which you can claim restart manufacture, i.e. your inactive registrations.

Figure 39: Restart manufacture search tab



Select the registration for which you wish to restart manufacture for and click the <Restart manufacture> button. The system will direct you to the <Details> tab.

Figure 40: Restart manufacture details tab



Read and agree with the declaration by ticking the checkbox. Click the <Next> button. The system will direct you to the <Confirmation> tab.

Version: 1.4 Page 39 of 41

Part 06 - Dossier submission



Figure 41: Restart manufacture confirmation tab



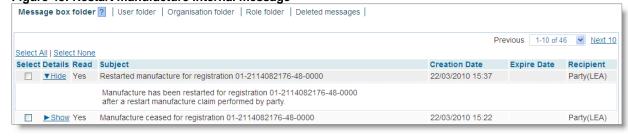
On the <Confirmation> tab, confirm your intention to restart manufacture for the selected registration by ticking the checkbox. Click the <Restart manufacture> button. The system will confirm that you have successfully restarted manufacture.

Figure 42: Restart manufacture confirmation message



You will also receive an internal message confirming the restart manufacture in your internal message box.

Figure 43: Restart manufacture internal message



Version: 1.4 Page 40 of 41

